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No. 06-1249

IN THE
SUPREME COURT OF THE UNITED STATES

WYETH,
Petitioner,

v.

DIANA LEVINE,
Respondent.

ON WRIT OF CERTIORARI TO
THE VERMONT SUPREME COURT

BRIEF *OF AMICI CURIAE* AARP, THE NATIONAL WOMEN'S HEALTH NETWORK, AND PRESCRIPTION ACCESS LITIGATION IN SUPPORT OF RESPONDENT

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STATEMENT OF INTEREST OF *AMICI CURIAE* [1/]

AARP is a nonpartisan, nonprofit organization with nearly forty million members, including members in each of the fifty states and the District of Columbia. AARP works to foster the health and economic security of individuals as they age. To that end, AARP supports efforts at state and national levels to ensure access to safe and effective health care services and products. AARP is greatly concerned about the safety of prescription drugs because older people disproportionately use them compared to their younger counterparts. AARP supports laws and public policies designed to protect its members' rights and to preserve the availability of legal redress when its members are harmed in the marketplace.

The National Women's Health Network (NWHN) is a nonprofit, nonpartisan organization with thousands of members nationwide that improves the health of all women by influencing policy and supporting informed consumer decision-making. The NWHN has a significant interest in protecting the health of women, who use the health care system more frequently than men, from injuries due to untested, unsafe and misbranded drugs. The NWHN believes

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[1/] This brief is being submitted with the consent of the parties. It was prepared on behalf of AARP, the National Women's Health Network, and Prescription Access Litigation by their undersigned counsel. It was not authored, in whole or in part, by counsel for any party. No person or entity other than AARP, the National Women's Health Network, and Prescription Access Litigation or their counsel made a monetary contribution to the preparation or submission of the brief.

that effective state tort law remedies are necessary to protect women from unsafe drugs.

The Prescription Access Litigation Project (PAL), a project of the nonpartisan nonprofit organization Community Catalyst, uses litigation and consumer education to challenge illegal pharmaceutical industry tactics. PAL is a coalition of over 130 state, local, and national organizations, including senior citizen groups, consumer advocates, health care advocates, legal services offices, nonprofit health plans, labor unions, and union benefit funds. The members of the PAL coalition have a combined membership of over 13 million individuals. A number of PAL member organizations are plaintiffs in lawsuits regarding drug marketing and advertising that involve preemption issues under the Federal Food, Drug, and Cosmetic Act.

Amici have a significant interest in this case. The issue before the Court could directly affect the ability of each organizations' members to seek redress when injured by dangerous pharmaceutical products that lack appropriate warnings about the risks of using those products. In addition, the Court's resolution of the preemption question in this case could have a broad impact on public safety regarding the use of prescription drugs. Petitioner seeks to eliminate the traditional role played by the tort system and leave the Food and Drug Administration ("FDA") as the sole protector of the American public with regard to drug safety. Yet the FDA lacks the resources, independence, and regulatory authority to perform this task on its own. As such, the practical

reality is that Petitioner's approach would sharply increase the public's risk of injury from inadequately labeled drugs. *Amici* have a strong interest in preventing this outcome, and can offer a different perspective on the issues before the Court than those of the parties.

Amici believe that the tort system should remain vibrant even if the FDA becomes more effective at promoting drug safety, and that partnership between a vibrant tort system and an effective regulatory agency will best protect the American public from inadequately labeled drugs. *Amici* fully support the arguments made by the Respondent and supporting *amici curiae* on these points. In order to prevent duplication of argument, however, this brief focuses solely on the FDA's shortcomings as the sole guarantor of public safety with respect to drug products.

SUMMARY OF ARGUMENT

The Petitioner argues the FDA possesses exclusive authority to protect the American public from unsafe drugs and to assure that prescription drugs are properly labeled. This position faces serious practical problems. First, the FDA simply does not have the resources to monitor effectively the performance of every marketed drug and to ensure that every drug's label adequately warns of the drug's risks. The FDA's lack of resources to protect the public from unsafe or inadequately labeled drugs has been noted by sources both within and without the agency, including the General Accounting Office, the Institute

of Medicine, and the FDA's own Science Board. These sources have emphasized the agency's inability to monitor the safety of drugs once they are on the market, and they have concluded that the FDA's ineffectiveness places American lives at risk. As one FDA employee bluntly stated, "the FDA and its Center for Drug Evaluation and Research are broken." *See* Testimony of David Graham before the U.S. Senate Finance Committee (Nov. 18, 2004) at 4 ("Graham Testimony"), available at http://finance.senate.gov/hearings/testimony/2004test/111804dgtest.pdf.

The FDA's capacity to ensure drug safety is limited not only by lack of resources, but also by its lack of independence from the pharmaceutical industry. Because the FDA does not have the capacity to conduct independent research regarding drug safety, it relies entirely on the pharmaceutical industry to perform the needed clinical research and provide the FDA with the results. The FDA then relies heavily on industry financing and personnel to support its review of industry-provided data. Numerous FDA scientists also have stated that commercial interests inappropriately influence FDA decisions regarding drug products, revealing yet another limitation on the FDA's ability to protect the public from unsafe or inadequately labeled drugs.

Finally, resource constraints aside, the FDA lacks effective regulatory authority to require manufacturers to strengthen warning labels to reflect newly-discovered risks. The FDA enjoyed no direct power to impose a post-approval labeling change until passage of the Food and Drug Amendments Act of

2007, Pub. L. No. 110-85, 121 Stat. 823 (the "FDAAA"). The FDAAA provides the FDA with some power in this regard, but the statute limits that power by requiring the FDA to undertake extensive negotiations with a drug's sponsor and by providing the FDA with no right of unilateral action. *See* 21 U.S.C. § 355(o). The authority provided by the FDAAA is further limited by the FDA's lack of resources, which disables the FDA from acting effectively across the full range of post-marketing safety issues.

Because of these practical limitations, the FDA is unable to assume sole responsibility for protecting the American public from inadequately labeled drugs. The Court should reject the Petitioner's approach, and preserve the historic relationship between the tort system and the FDA with regard to ensuring that drugs are safe and properly labeled.

ARGUMENT

I. The FDA lacks the resources to ensure drug safety.

The pro-preemption position advanced by the Petitioner and its *amici* faces a serious practical problem: it is based on an unrealistic assessment of the FDA's actual ability to detect the unforeseen adverse effects of an approved drug and to take appropriate remedial action. As a former FDA Commissioner recently wrote, "[t]he reality is that the FDA does not have the resources to perform the Herculean task of monitoring comprehensively the performance of every drug on the market." David A.

Kessler and David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461, 484-85 (2008).

The FDA's practical ability to monitor the performance of marketed drugs is of immense public health importance, especially because of the limited information available to the agency before approval about a new drug's risks and potential adverse effects. Pre-approval clinical studies of a new drug typically involve carefully controlled study conditions and at most a few thousand subjects who do not represent the full array of patients who will use the drug when it is placed on the market. *See id.* at 466. Often, only after a drug enters the marketplace do the drug's full range of risks become apparent, including risks that are rare, affect specific sub-populations, or manifest themselves only over long periods of time. *See id.* The FDA simply lacks sufficient resources to keep pace with this emerging information and to take effective remedial action when a drug proves to be inadequately labeled, as set forth further below.

The FDA unit tasked with reviewing and monitoring pharmaceutical products is the Center for Drug Evaluation and Research ("CDER"). This unit has limited personnel and funding for post-marketing drug safety. With regard to personnel, CDER's Office of Drug Safety ("ODS") employs only 100 people to monitor post-marketing drug safety for over 11,000 FDA-approved drugs, including over 3,000 prescription drugs, in a country whose doctors write in excess of 3.3 billion prescriptions per year. *See id.*; FDA Science Mission at Risk, Report of the Subcommittee on

Science and Technology at 11 (Nov. 2007) (the "FDA Science Board Report"), available at http://www.fda.gov/ohrms/dockets/AC/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf. In contrast, reflecting the FDA's prioritization of the drug approval process, approximately ten times as many employees work in CDER's Office of New Drugs ("OND"), which primarily reviews applications for new drugs and approves approximately 100 new drugs each year. *See* Kessler and Vladeck, 96 Geo. L.J. at 485; United States Government Accountability Office, *Report to Congressional Requesters: Drug Safety – Improvement Needed in FDA's Post-Market Decision-Making and Oversight Process* at 14 (March 2006) (the "GAO Report").

The financial resources devoted to monitoring the safety of marketed drugs are similarly weak, partly because of the Prescription Drug User Fee Act of 1992 ("PDUFA"), Pub. L. No. 102-571, 106 Stat. 4491. PDUFA was enacted to accelerate the review of new drug applications. It placed strict timelines on the review process in exchange for user fees from the companies seeking the FDA's approval of new drugs. Although PDUFA successfully decreased the FDA's review times for new drugs, its initial versions prohibited the use of fees for any post-marketing drug safety activities. Congress eased restrictions on the FDA's use of PDUFA funds when reauthorizing the statute in 2002, but the resource disparity remains: ODS had 2005 expenditures of only $26.9 million, whereas OND had 2005 expenditures of $110.6

million, more than four times as much. *See* GAO Report at 8.

Thus, the FDA has barely 100 employees to monitor the post-approval performance of 11,000 drugs (over 100 drugs per employee), and those employees are supported by funding levels less than one quarter of the amount devoted to new drug approval. Given this data, it is not surprising that FDA's own employees have questioned the agency's ability to ensure the safety of prescription drugs on the market. In 2004, FDA Drug Safety Officer David Graham, M.D., M.P.H., gave congressional testimony placing the FDA's ineffective response to reports of increased cardiac adverse events among Vioxx users into a broad context:

> Vioxx is a terrible tragedy and a profound regulatory failure. I would argue that the FDA, as currently configured, is incapable of protecting America against another Vioxx. We are virtually defenseless. It is important that this Committee and the American people understand that what happened with Vioxx is really a symptom of something far more dangerous to the safety of the American people. Simply put, the FDA and its Center for Drug Evaluation and Research are broken.

See Graham Testimony at 4 (emphasis added). Dr. Graham's concern that the FDA is "broken" regarding post-marketing drug safety is widely shared by the

FDA's professional staff. In 2006, the Union of Concerned Scientists ("UCS") polled FDA scientists on a range of issues. The poll found that 66% of respondents were "not at all confident" or only "somewhat confident" that the FDA adequately monitored the safety of prescription drugs after they reached the market. *See* UCS 2006 Food and Drug Administration Survey ("UCS Survey"), available at www.ucsusa.org/assets/documents/scientific_integrity/Additional-Questions-and-Responses.pdf. The poll also found that 42% of the survey respondents were "not at all confident" or only "somewhat confident" that the FDA's final decisions adequately assessed drug safety. *See id.*

Independent evaluators have reached similar conclusions. In March 2006, the GAO reported to Congress on the FDA's oversight of drug safety. *See* GAO Report, *supra*. There, the GAO sharply criticized the FDA's ability to respond effectively to post-marketing safety issues:

> The FDA lacks clear and effective processes for making decisions about, and providing management oversight of, postmarket safety issues. The process is limited by a lack of clarity about how decisions are made and about organizational roles, insufficient oversight by management, and data constraints. [GAO] observed a lack of criteria for determining what safety actions to take and when to take them.

> ....
>
> Some of FDA's initiatives, such as the establishment of a Drug Safety Oversight Board (DSB), a draft policy on major postmarket drug safety decision making, and the identification of new data sources, may improve the postmarket drug safety decision-making process, but they will not address all the gaps we identified.

Id. at 5.

The Institute of Medicine ("IOM"), a non-profit society chartered by Congress to advise the federal government on scientific and technical matters, also has identified serious problems with the FDA's oversight of drug safety. In 2004, the FDA contracted with IOM to examine its regulation of drug safety in light of public health failures (such as Vioxx) that called into question FDA's capacity to evaluate drug safety. IOM published a massive study in September 2006 that highlighted the FDA's lack of resources as an impediment to the FDA's ability to act effectively:

> The [FDA] lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future. Despite the fact that so much has changed in drug discovery and development, in the number and complexity of FDA's Congressionally mandated

> responsibilities, in the practice of medicine, the structuring and delivery of health care, the way drugs are used, the role of patients and consumers, and the information environment, FDA appropriations for new drug reviews have remained roughly flat (in constant dollars) since the passing of the Prescription Drug User Fee Act (PDUFA) (GAO, 2002; Thompson, 2000). User-fees have led to an overall increase in resources for new drug review, but activities not funded by user fees have received a smaller portion of FDA's total budget. There is little dispute that FDA in general is, and CDER specifically remains, severely underfunded (Goldhammer A, 2005; Wolfe S, 2006).

Institute of Medicine of the National Academies, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* at 7-1 (Alina Baciu, Kathleen Stratton and Sheila P. Burke, eds., 2006) ("IOM Report").

The IOM Report specifically expressed concern about the inadequate funding for post-marketing drug safety:

> There is widespread agreement that resources for postmarketing drug safety work are especially inadequate and that resource limitations have hobbled the agency's ability to improve and expand

> this essential component of its mission. Continued resource shortages will impede the agency's ability to use new and future scientific and technological advances in drug research across the lifecycle. In particular, the limited resources could impede the agency's ability to detect risks of new drugs in a timely fashion, analyze emerging drug safety data, and effectively communicate that information to the public in the ways envisioned in the committee's report.

Id.

Many of the FDA's own doctors and scientists share the IOM's concern. Seventy percent of respondents to the 2006 UCS Survey mentioned above stated that the FDA lacks sufficient resources to protect public health, and two-thirds of respondents worried that the FDA cannot adequately monitor the safety of drugs once they are on the market. *See* UCS Survey, *supra*. This level of concern is long-standing: approximately the same percentage of FDA doctors and scientists expressed such views in response to a 2003 poll conducted by the Office of the Inspector General of the Department of Health and Human Services. *See* Office of the Inspector General, Department of Health and Human Services, *FDA's Review Process for New Drug Applications: A Management Review* at 12, 19 (2003), available at http://www.fda.gov/ola/2005/ drugsafety0301.html.

The FDA's own Science Board has expressed similar alarm about the agency's ability to protect the public from pharmaceutical products. In December 2006, the FDA Commissioner asked its Science Board to form a Subcommittee to assess whether science and technology at the FDA could support current and future regulatory needs. The Science and Technology Subcommittee consisted of members of the Science Board and experts representing industry, academia, and other government agencies.

In a 2006 report titled "FDA Science and Mission at Risk," the Subcommittee found that demands placed on the FDA have increased dramatically due to the advance of scientific discoveries, the complexity of new products submitted for the FDA's review, the emergence of challenging safety problems, and the globalization of the industries that the FDA regulates. *See* FDA Science Board Report at 3. At the same time, the Subcommittee concluded, "the scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity of the food, drug, cosmetic and device regulatory system, and hence the safety of the public." *Id.* at 2. In particular, the Subcommittee found that the FDA's scientific base has eroded and its scientific organization structure is unacceptably weak. "Today, not only can the Agency not lead, it cannot even keep up with the advances in science." *Id.* at 3. Moreover, because the FDA's scientific workforce lacks expertise in numerous fields, "the FDA is ineffective in responding to emerging fields that require individuals and work teams with multidisciplinary skills built on very complex, highly

specialized, often esoteric bodies of knowledge." *Id.* at 5. The Subcommittee also found that the FDA's information technology infrastructure is so antiquated and unstable that "[t]he IT situation at FDA is problematic at best – and at worst it is dangerous." *Id.* at 5. The Subcommittee bluntly addressed the FDA's funding problems: "In contrast to previous reviews that warned crises would arise if funding issues were not addressed, recent events and our findings indicate that some of those crises are now realities and American lives are at risk." *Id.* at 6 (emphasis added).

The Subcommittee discussed the above problems specifically in the context of post-marketing drug safety. The Subcommittee specifically found that "[t]he FDA lacks sufficient expertise to understand the impact of [drug] product use, to maintain ongoing currency with their evolution or to evaluate the sophisticated products produced. In addition, the FDA has no consistent strategy to acquire that expertise." *Id.* at 24. These deficiencies, the Subcommittee said, are compounded by the agency's inadequate information technology infrastructure, which cannot effectively manage the large amounts of data created by emerging sciences (such as genomics, proteomics, and metabolomics) in support of product design, testing, and ongoing safety analysis. *See id.* at 25-26.

These grim conclusions have been echoed by Subcommittee member Peter Barton Hutt, a former Chief Counsel of the FDA. During recent congressional testimony, Mr. Hutt stated that "[s]cience at the Food and Drug Administration (FDA) today is in a precarious position. In terms of both

personnel and the money to support them, the agency is barely hanging on by its fingertips." *See* Testimony of Peter Barton Hutt before the U.S. House Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce (Jan. 29, 2008) at 1, available at http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.012908.Hutt-Testimony.pdf (emphasis added). Mr. Hutt added that "FDA has become a paradigmatic example of the 'hollow government' syndrome – an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates." *Id.* at 2.

None of this has been lost on Congress. In January 2008, three Senators and five Representatives, all committee chairs, wrote the FDA Commissioner about an FDA effort to limit the circumstances under which companies must update drug labels with new safety information. Criticizing the effort, the authors emphasized the FDA's dire funding situation:

> Since 1982, FDA's funding situation has taken a dramatic turn for the worse. Today, FDA is an agency that is all but starved of resources. Experts from every affected sector agree that this desperate funding situation has rendered FDA unable to protect the American public from even the most basic threats, including contaminated food, tainted and dangerous drugs, and faulty medical devices. According to FDA's own Science

> Board, FDA's ability to carry out its mission is so compromised by loss of resources that American lives are now at risk.

See Correspondence from Senators Leahy, Kennedy and Dodd and from Representatives Waxman, Dingell, Markey, Pallone, and DeLauro, dated Jan. 23, 2008, available at http://oversight.house.gov/documents/20080123120931.pdf.

In short, the Petitioner advances a preemption argument with the implicit premise that Americans can rely on the FDA to ensure that drugs are appropriately labeled. This premise is faulty in large part because the FDA is so inadequately funded and understaffed with respect to protecting drug safety. That risk will only increase if the FDA is forced to be the sole guarantor of drug safety.

II. The FDA lacks the independence to ensure drug safety.

Because of its limited resources, the FDA must rely on the industry it regulates to perform essential functions of the FDA's mission. For example, the agency relies entirely on the pharmaceutical industry to perform clinical research on drugs being reviewed; the agency does not conduct independent research on a drug's capabilities or adverse effects. *See* IOM Report at 2-4. This reality is not without consequences. As two former editors-in-chief of the New England Journal of Medicine have observed, "[c]ompanies now often insist on controlling how the

research is done and reported, and whether the result will even be published at all" under "financial arrangements with academic medical centers and their faculties . . . that threaten the objectivity and credibility of clinical research." Marcia Angell & Arnold S. Relman, Op-Ed, *Prescription for Profit*, Wash. Post, June 20, 2001, at A27. In other words, the FDA sees only what a drug company provides with regard to clinical testing of a pharmaceutical product, and that information may not even be reliable.

Not only does the FDA receive only those materials that the drug companies provide, but the FDA relies heavily on drug companies to finance the agency's review of that material. In 2004, for example, more than half of the FDA's budget for review of drug applications for human drugs was obtained from industry-provided user fees. *See* FY 2004 PDUFA Financial Report Required by the PDUFA, at 9 (March 2005), available at www.fda.gov/oc/pdufa/finreport2004.

Further, many of FDA's scientific personnel have said that commercial interests routinely affect the FDA's decision-making process. Sixty percent of FDA scientists responding to the 2006 UCS Poll knew of cases where commercial interests inappropriately influenced FDA approvals or other decisions. *See* Union of Concerned Scientists, *Voices of Scientists at FDA: Protecting Public Health Depends on Independent Science* at 2 (2006), available at http://www.ucsusa.org/scientific_integrity/interference/fda-scientists-survey-summary.html. One-fifth of the survey respondents also reported being "asked

explicitly by FDA decision-makers to provide incomplete, inaccurate or misleading information to the public, regulated industry, media, or elected/senior government officials." *Id.* Overall, FDA's scientists reported "significant interference with the FDA's scientific work." *See id.* at 1.

The FDA relies not only on industry money, but also frequently on industry scientists to advise the FDA on a drug's risks and benefits. Unfortunately, these scientists are often subject to unacceptable conflicts of interest. A recent study published in the Journal of the American Medical Association found that almost one-third of the scientists on product review panels had financial interests exceeding $50,000 in the company whose products they were responsible for evaluating. *See* Peter Lurie et al., *Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings*, 295 J. Am. Med. Ass'n 1921, 1924 (2006). The study also found that more than one-fifth of product review panels included a majority of scientists with a conflict of interest, and that nearly three-quarters of such panels included at least one scientist with a conflict of interest. *See id.*

The FDA's lack of independence from the pharmaceutical industry necessarily weakens the FDA's ability to monitor and promote drug safety. The danger to the public created by this lack of independence will increase if the FDA becomes the sole guarantor of drug safety.

III. The FDA lacks the regulatory tools to ensure drug safety.

Finally, resource constraints aside, the FDA lacks effective regulatory authority to require a manufacturer to enhance a drug's warnings after the drug has gone on the market. This further limits the FDA's ability to ensure that drugs are safe and appropriately labeled.

By way of background, since the passage of the Food, Drug and Cosmetic Act in 1938, all drugs must be evaluated and approved by the FDA before they may be marketed in the United States. Since 1962, a drug's sponsor must obtain FDA approval that a new drug is safe and effective for its approved uses and that its labeling is not false or misleading. *See* 21 U.S.C. § 355. The FDA's review of a new drug includes examination of the drug's label, which must accurately and fairly describe the drug's intended uses and must discuss its potential risks, contraindications, warnings, precautions and adverse reactions. *See* 21 U.S.C. § 355(d); 21 C.F.R. §§ 201.56, 201.57, 201.80.

To obtain FDA approval for a new drug, the drug's sponsor must perform clinical studies bearing on the drug's safety and effectiveness, and provide the results of those studies in a "New Drug Application." *See* 21 U.S.C. § 355. Unfortunately, pre-approval clinical studies typically involve carefully controlled study conditions and at most a few thousand subjects who may not represent the full array of patients who will use the drug when it is placed on the market. *See* IOM Report at 2-6, 2-7. As a result, clinical studies

often are incapable of detecting unforeseen and serious side-effects that will not become apparent until the drug is widely prescribed by doctors, even where the drug is properly used for its approved purposes. *See id.*; Kessler and Vladeck, 96 Geo. L.J. at 470.

Because of the likelihood that unforeseen adverse effects will manifest after a drug is on the market, FDA regulations enable a drug's sponsor to enhance the drug's label without FDA's pre-approval. *See* 21 C.F.R. §§ 201.57(c)(6), 201.80(e), 314.70(c). Unfortunately, the FDA historically has had no authority to impose a post-approval labeling change on a manufacturer unwilling to meet its responsibilities. Instead, the FDA has been forced to negotiate with manufacturers on labeling issues, using as leverage its powers to seek withdrawal of dangerous drugs from the market or to file a misbranding action. *See* 21 U.S.C. §§ 331, 355(e). Unfortunately, these powers are too drastic to be used with any frequency, crippling the FDA's leverage to force a desired change. For example, since 2000, there have been only 10 drug withdrawals for safety reasons, and in each case the drug's sponsor voluntarily removed the drug from the market. *See* GAO Report at 10 (noting that the FDA has forcibly withdrawn a drug only once in its history). As for misbranding claims, the FDA has <u>never</u> filed a misbranding claim against a manufacturer on grounds that a drug's warnings were inadequate. *See* Vladeck and Kessler, 96 Geo. L.J. at 479-80 (noting that misbranding actions are resource intensive and difficult to prove). Because drug manufacturers know there is little credibility to an FDA threat that it will forcibly remove drugs from the market or commence a

misbranding action on labeling issues, the FDA lacked a strong negotiating position, resulting in compromise agreements that provide the public with less protection than the FDA initially sought. *See id.* at 480 and note 82.

This situation is not dramatically improved by recent Congressional action to strengthen the FDA's authority. Recognizing that regulatory deficiencies have contributed to the FDA's overall ineffectiveness, Congress recently enacted the FDAAA, *inter alia*, to provide the FDA with some authority to prompt manufacturers to make labeling changes. *See* 21 U.S.C. § 355(o). Unfortunately, the statute limits that power by requiring the FDA to undertake negotiations with a drug manufacturer before taking action, and by failing to provide the FDA with the power to act unilaterally or immediately. The FDAAA alone is not a warrant to jettison the tort system.

By way of further explanation, the FDAAA requires the FDA to notify a drug's manufacturer if the agency becomes aware of new safety information the agency believes should be included in a drug's labeling. *See* 21 U.S.C. § 355(o)(4)(A). Following the notification, the manufacturer has thirty days either to propose label changes reflecting the new safety information or to notify the FDA that it does not believe labeling changes are warranted. *See* 21 U.S.C. § 355(o)(4)(B). If the FDA disagrees with the manufacturer's response, the FDA must initiate "discussions" to reach agreement with the manufacturer. *See* 21 U.S.C. § 355(o)(4)(C). These discussions supposedly may not extend more than

thirty days, but the FDA has the authority to grant an extension. *See* 21 U.S.C. § 355(o)(4)(D). If the discussions result in agreement, that is the end of the matter; if they do not, then the FDA has fifteen days to order the manufacturer to make the changes the FDA deems appropriate. *See* 21 U.S.C. § 355(o)(4)(E). The manufacturer has five days within which to accede or file an appeal using dispute resolution procedures established by the FDA. *See* 21 U.S.C. § 355(o)(4)(F). If at the end of the appeal process, the FDA still concludes that changes are required to the label, the manufacturer must submit a supplement within fifteen days. *See* 21 U.S.C. § 355(o)(4)(G). Significantly, the statute does not enable the FDA to act unilaterally or immediately, although it gives the FDA power to "accelerate" the timelines where "a labeling change is necessary to protect the public health." 21 U.S.C. § 355(o)(4)(H).

This elaborate procedure raises practical questions about the efficacy of the statute. Because the FDA lacks sufficient resources to monitor drug safety effectively, the agency may never know that a drug needs enhanced warnings, or it may not initiate the FDAAA process in a timely fashion, or it may initiate the process but accept a poor compromise because other tasks call for attention. The statute also does nothing to address the ongoing influence of commercial interests on the FDA's decision-making process. The new authority provided by the FDAAA is limited where the FDA lacks the resources and independence to act effectively across the full range of drug safety issues. In any event, as the FDAAA did not exist at the time of the events giving rise to this

case, its bearing on this Court's analysis should be limited at best.

* * *

The Petitioner invites this Court to leave drug safety solely to the care of the FDA, an agency so constrained by lack of funding, personnel, and scientific expertise that "American lives are now at risk." FDA Science Board Report at 6. This Court should reject that invitation, and preserve the historic partnership between the FDA and tort system with regard to promoting public safety.

CONCLUSION

The judgment of the Vermont Supreme Court should be affirmed.

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Respectfully submitted,

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